

**IN THE UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF NEW YORK**

SEAN BRAZIL,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 1:16-CV-271 (NRB)
	)	
BRISTOL-MYERS SQUIBB	)	
COMPANY, et al.,	)	
	)	
Defendants.	)	

**DEFENDANT BRISTOL-MYERS SQUIBB COMPANY’S  
ANSWER TO PLAINTIFF’S COMPLAINT AND JURY DEMAND**

Defendant Bristol-Myers Squibb Company (“BMS”), by and through undersigned counsel, hereby answers Plaintiff’s Complaint (the “Complaint”).

As to each allegation, BMS responds as follows. All allegations are denied unless specifically admitted. To the extent that the Introduction, the headings used in the Complaint, or Plaintiff’s Prayer for Relief require a response, BMS denies the allegations therein.

1. To the extent Paragraph 1 is intended to summarize allegations set forth in Plaintiff’s Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, BMS admits that Plaintiff brings this suit involving the prescription drug Abilify®, but denies that Plaintiff is entitled to any relief against BMS whatsoever.

2. Answering the allegations of Paragraph 2, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS states that the U.S. Food and Drug Administration (“FDA”) has determined that

Abilify® is safe and effective for use in accordance with its FDA-approved label, and that label speaks for itself. BMS denies the remaining allegations in Paragraph 2.

3. BMS denies the allegations in Paragraph 3.

4. BMS denies the allegations in Paragraph 4.

5. Answering the allegations of Paragraph 5, BMS states that the European and Canadian labels for Abilify® speak for themselves. BMS denies the remaining allegations in Paragraph 5.

6. BMS denies the allegations in Paragraph 6.

### **PARTIES**

7. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 7 and therefore denies the same.

8. To the extent Paragraph 8 alleges that Plaintiff was prescribed and took Abilify®, and to the extent Paragraph 8 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. BMS denies the remaining allegations in Paragraph 8.

9. To the extent Paragraph 9 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. BMS denies the remaining allegations in Paragraph 9.

10. BMS denies the allegations in Paragraph 10.

11. BMS admits the allegations in Paragraph 11.

12. Answering the allegations of Paragraph 12, BMS states that Otsuka America Pharmaceutical, Inc. is a subsidiary of the Japanese pharmaceutical manufacturer Otsuka Pharmaceutical Co., Ltd. and that Abilify® is a trademark of Otsuka Pharmaceutical Co., Ltd.

BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 12 and therefore denies the same.

13. Answering the allegations of Paragraph 13, BMS states that Otsuka America Pharmaceutical, Inc. has distributed and marketed Abilify® in the United States. BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 13 and therefore denies the same.

14. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 14 and therefore denies the same.

15. Answering the allegations of Paragraph 15, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS denies the remaining allegations in Paragraph 15.

16. Answering the allegations of Paragraph 16, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS further states that the FDA approved Abilify® for sale in the United States in 2002, and that Abilify® was approved for sale in Japan in 2006. BMS denies the remaining allegations in Paragraph 16.

17. Answering the allegations of Paragraph 17, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS denies the remaining allegations in Paragraph 17.

### **JURISDICTION**

18. The allegations in Paragraph 18 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

19. The allegations in Paragraph 19 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

20. The allegations in Paragraph 20 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

21. The allegations in Paragraph 21 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

22. To the extent Paragraph 22 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. The remaining allegations in Paragraph 22 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

#### **FACTUAL BACKGROUND**

23. BMS admits the allegations in Paragraph 23.

24. Answering the allegations in Paragraph 24, BMS states that the European Medicines Agency document speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations in Paragraph 24.

25. Answering the allegations in Paragraph 25, BMS states that European label for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations in Paragraph 25.

26. Answering the allegations in Paragraph 26, BMS states that the European label for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 26.

27. Answering the allegations in Paragraph 27, BMS states that the cited Health Canada documents speak for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations of Paragraph 27.

28. Answering the allegations in Paragraph 28, BMS states that the Canadian prescribing information for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 28.

29. BMS denies the allegations in Paragraph 29.

30. BMS denies the allegations in Paragraph 30.

31. To the extent the allegations of Paragraph 31 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS denies the same. BMS denies the remaining allegations in Paragraph 31.

32. Answering the allegations in Paragraph 32, BMS states that the cited website and press release speak for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations in Paragraph 32.

33. Answering the allegations of Paragraph 33, BMS states that the FDA has determined that Abilify® is safe and effective for use in accordance with its FDA-approved label, and the label speaks for itself. BMS denies the remaining allegations in Paragraph 33.

34. Answering the allegations in Paragraph 34, BMS states that Abilify® is an atypical antipsychotic with the generic name aripiprazole, and FDA approved Abilify® for treatment of schizophrenia in 2002. BMS further states that the New Drug Application for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 34.

35. Answering the allegations in Paragraph 35, BMS states that the FDA approval letter speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 35.

36. Answering the allegations in Paragraph 36, BMS states that the Supplemental New Drug Application speaks for itself, and any attempt to characterize it is denied. BMS further states that the FDA approved longer-term efficacy of Abilify® for the treatment of schizophrenia in 2003. BMS denies the remaining allegations of Paragraph 36.

37. Answering the allegations in Paragraph 37, BMS states that the Supplemental New Drug Application speaks for itself, and any attempt to characterize it is denied. BMS further states that the FDA approved Abilify® for the treatment of bipolar disorder in 2004. BMS denies the remaining allegations of Paragraph 37.

38. Answering the allegations in Paragraph 38, BMS states that the Supplemental New Drug Application speaks for itself, and any attempt to characterize it is denied. BMS further states that the FDA approved Abilify® for the treatment of major depressive disorder in 2007. BMS denies the remaining allegations of Paragraph 38.

39. Answering the allegations in Paragraph 39, BMS states that the European label for Abilify® sets forth its indications and speaks for itself. BMS denies the remaining allegations of Paragraph 39.

40. Answering the allegations in Paragraph 40, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States and Europe. BMS denies the remaining allegations of Paragraph 40.

41. Answering the allegations in Paragraph 41, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS denies the remaining allegations of Paragraph 41.

42. Answering the allegations in Paragraph 42, BMS states that the FDA approved Abilify® for sale in the United States and Puerto Rico in 2002. BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS denies the remaining allegations of Paragraph 42.

43. Answering the allegations in Paragraph 43, BMS states that it collaborated with Otsuka America Pharmaceutical, Inc. in the commercialization of Abilify® in the United States. BMS further states that the patent protection for Abilify® expired in April 2015. BMS denies the remaining allegations of Paragraph 43.

44. BMS denies the allegations in Paragraph 44.

45. BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 45 and therefore denies the same.

46. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 46 and therefore denies the same.

47. Answering the allegations in Paragraph 47, BMS states that the clinical pharmacology of Abilify® is set forth in the FDA-approved label for Abilify®. Except as stated in the FDA-approved label for Abilify®, BMS denies the allegations in Paragraph 47.

48. Answering the allegations in Paragraph 48, BMS states that the cited studies speak for themselves, and any attempts to characterize them are denied. BMS denies the remaining allegations of Paragraph 48.

49. Answering the allegations in Paragraph 49, BMS states that the clinical pharmacology of Abilify® is set forth in the FDA-approved label for Abilify®. Responding further, BMS states that the allegations of this paragraph appear to refer to documents in the “scientific literature,” the referenced documents speak for themselves and BMS denies any characterization of, or commentary about the cited documents. Except as stated, BMS denies the remaining allegations of Paragraph 49.

50. Answering the allegations in Paragraph 50, BMS states that the September 2011 6-Month Periodic Safety Update Report speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 50.

51. Answering the allegations in Paragraph 51, BMS states that the September 2011 6-Month Periodic Safety Update Report speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 51.

52. Answering the allegations in Paragraph 52, BMS states that the September 2011 6-Month Periodic Safety Update Report speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 52.

53. Answering the allegations in Paragraph 53, BMS states that the European Final Assessment Report speaks for itself and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 53.

54. Answering the allegations in Paragraph 54, BMS states that the cited case reports speak for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations of Paragraph 54.

55. Answering the allegations in Paragraph 55, BMS states that the cited case reports speak for themselves, and any attempt to characterize them is denied. BMS lacks



knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 55 and therefore denies the same.

56. Answering the allegations in Paragraph 56, BMS states that the cited FDA guidance document speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 56.

57. Answering the allegations in Paragraph 57, BMS states that the cited FDA guidance document speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 57.

58. Answering the allegations in Paragraph 58, BMS states that the cited FDA guidance document speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 58.

59. Answering the allegations in Paragraph 59, BMS states that the cited FDA guidance document and Federal Judicial Center Reference Manual speak for themselves, and any attempts to characterize them are denied. BMS denies the remaining allegations of Paragraph 59.

60. Answering the allegations in Paragraph 60, BMS states that the cited adverse event reports speak for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations of Paragraph 60.

61. The allegations in Paragraph 61 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS states that the cited regulation speaks for itself and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 61.

62. Answering the allegations in Paragraph 62, BMS states that the FDA report speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 62.

63. Answering the allegations in Paragraph 63, BMS states that the cited study speaks for itself, and any attempt to characterize it is denied. BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 63 and therefore denies the same.

64. Answering the allegations in Paragraph 64, BMS states that the FDA Adverse Event Reporting System, and any data or reports therein, speaks for itself, and any attempt to characterize it is denied. BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 64 and therefore denies the same.

65. Answering the allegations in Paragraph 65, BMS states that the FDA Adverse Event Reporting System, and any data or reports therein, speaks for itself, and any attempt to characterize it is denied. BMS lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 65 and therefore denies the same.

66. Answering the allegations in Paragraph 66, BMS states that any clinical trials comparing Abilify® to other schizophrenia drug speak for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations of Paragraph 66.

67. BMS denies the allegations in Paragraph 67.

68. Answering the allegations in Paragraph 68, BMS states that the study by the Cochrane Collaboration speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 68.

69. Answering the allegations in Paragraph 69, BMS states that the FDA-approved label for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 69.

70. Answering the allegations in Paragraph 70, BMS states that the terms of any civil settlement agreements with the United States Department of Justice (“DOJ”), and any public announcement by the DOJ regarding the same, speak for themselves. BMS denies the remaining allegations in Paragraph 70.

71. Answering the allegations in Paragraph 71, BMS states that the April 17, 2015 letter from FDA speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 71.

72. Answering the allegations of Paragraph 72, BMS states that it has employed pharmaceutical sales representatives who visit doctors and have discussed a variety of pharmaceutical products including Abilify®. BMS denies the remaining allegations in Paragraph 72.

73. Answering the allegations of Paragraph 73, BMS states that it has engaged in Direct-to-Consumer advertising. BMS denies the remaining allegations in Paragraph 73.

74. BMS denies the allegations in Paragraph 74.

75. BMS denies the allegations in Paragraph 75.

76. BMS denies the allegations in Paragraph 76.

77. BMS denies the allegations in Paragraph 77.

78. Answering the allegations in Paragraph 78, BMS states that the FDA-approved label for Abilify® sets forth its risk information and speaks for itself. BMS denies the remaining allegations of Paragraph 78.

79. Answering the allegations in Paragraph 79, BMS states that the FDA-approved label for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 79.

80. Answering the allegations in Paragraph 80, BMS states that the FDA-approved label for Abilify® speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations in Paragraph 80.

81. Answering the allegations in Paragraph 81, BMS states that the FDA-approved label for Abilify® and the European and Canadian labels speaks for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations in Paragraph 81.

82. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 82 and therefore denies the same.

83. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 83 and therefore denies the same.

84. Answering the allegations in Paragraph 84, BMS states that the BMS website speaks for itself, and any attempt to characterize it is denied. BMS denies the remaining allegations of Paragraph 84.

85. BMS lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 85 and therefore denies the same.

**EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

86. The allegations in Paragraph 86 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

87. The allegations in Paragraph 87 assert legal conclusions to which no response is required. To the extent a response is deemed necessary, BMS denies the same.

88. To the extent Paragraph 88 alleges what Plaintiff did or knew, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. BMS denies the remaining allegations in Paragraph 88.

89. BMS denies the allegations in Paragraph 89.

90. To the extent the allegations of Paragraph 90 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS denies the same. BMS denies the remaining allegations in Paragraph 90.

91. To the extent Paragraph 91 alleges what Plaintiff knew, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 91 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 91.

### **FIRST CAUSE OF ACTION**

#### **Strict Liability - Design, Manufacturing and Warning**

92. Answering the allegations of Paragraph 92, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

93. To the extent the allegations of Paragraph 93 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the warnings for and design and testing of Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 93.

94. BMS denies the allegations in Paragraph 94.

95. BMS denies the allegations in Paragraph 95.

96. BMS denies the allegations in Paragraph 96.

97. BMS denies the allegations in Paragraph 97.

98. BMS denies the allegations in Paragraph 98.

99. BMS denies the allegations in Paragraph 99.

100. BMS denies the allegations in Paragraph 100.

101. BMS denies the allegations in Paragraph 101.

102. To the extent Paragraph 102 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 102 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 102.

**SECOND CAUSE OF ACTION**  
**Breach of Express Warranty by Defendants**

103. Answering the allegations of Paragraph 103, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

104. The allegations in Paragraph 104 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS lacks knowledge or information sufficient to form a belief as to what warranties, if any, were made to Plaintiff and/or Plaintiff's physicians and therefore denies the allegations in Paragraph 104.

105. The allegations in Paragraph 105 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS denies the allegations in Paragraph 105.

106. BMS denies the allegations in Paragraph 106.

107. To the extent Paragraph 107 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 107 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 107.

**THIRD CAUSE OF ACTION**  
**Breach of Implied Warranty**

108. Answering the allegations of Paragraph 108, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

109. To the extent Paragraph 109 alleges that Defendants knew of the uses for which Abilify® was intended, BMS states that the FDA-approved label for Abilify® sets forth its indications and speaks for itself. BMS denies the remaining allegations in Paragraph 109.

110. BMS denies the allegations in Paragraph 110.

111. To the extent Paragraph 111 alleges upon what Plaintiff or her physicians relied, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. BMS denies the remaining allegations in Paragraph 111.

112. BMS denies the allegations in Paragraph 112.

113. BMS denies the allegations in Paragraph 113.

114. To the extent Paragraph 114 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 114 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 114.

**FOURTH CAUSE OF ACTION**

**Negligence**

115. Answering the allegations of Paragraph 115, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

116. To the extent the allegations of Paragraph 116 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the manufacture, design, and sale of Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 116.

117. To the extent the allegations of Paragraph 117 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the warnings for Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 117.

118. BMS denies the allegations in Paragraph 118.

119. BMS denies the allegations in Paragraph 119.

120. BMS denies the allegations in Paragraph 120, including all subparts thereof.

121. To the extent Paragraph 121 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 121 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 121.



**FIFTH CAUSE OF ACTION**

**Negligence Per Se**

**(Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)**

122. Answering the allegations of Paragraph 122, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

123. To the extent the allegations of Paragraph 123 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the manufacture, design, and sale of Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 123.

124. BMS denies the allegations in Paragraph 124, including all subparts thereof.

125. Answering the allegations of Paragraph 125, BMS states that the statutes and regulations speaks for themselves, and any attempt to characterize them is denied. BMS denies the remaining allegations in Paragraph 125.

126. BMS denies the allegations in Paragraph 126.

127. To the extent Paragraph 127 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 127 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 127.

**SIXTH CAUSE OF ACTION**

**Negligent Misrepresentation**

128. Answering the allegations of Paragraph 128, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

129. BMS denies the allegations in Paragraph 129.

130. BMS denies the allegations in Paragraph 130.

131. BMS denies the allegations in Paragraph 131.

132. BMS denies the allegations in Paragraph 132.

133. BMS denies the allegations in Paragraph 133.

134. BMS denies the allegations in Paragraph 134.

135. To the extent Paragraph 135 alleges what Plaintiff and/or her physicians believed, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. BMS denies the remaining allegations in Paragraph 135.

136. To the extent Paragraph 136 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 136 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 136.

#### **SEVENTH CAUSE OF ACTION**

##### **Violation of New York Consumer Protection Laws**

137. Answering the allegations of Paragraph 137, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

138. BMS denies the allegations in Paragraph 138.

139. BMS denies the allegations in Paragraph 139.

140. To the extent Paragraph 140 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 140 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 140.

**EIGHTH CAUSE OF ACTION**  
**Fraudulent Concealment**

141. Answering the allegations of Paragraph 141, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

142. BMS denies the allegations in Paragraph 142.

143. BMS denies the allegations in Paragraph 143.

144. To the extent the allegations of Paragraph 144 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the manufacture, design, and sale of Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 144, including all subparts thereof.

145. To the extent the allegations of Paragraph 145 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, BMS states that the legal duties concerning the manufacture, design, and sale of Abilify® are governed by applicable laws and regulations. BMS denies the remaining allegations in Paragraph 145.

146. BMS denies the allegations in Paragraph 146.

147. BMS denies the allegations in Paragraph 147.

148. To the extent Paragraph 148 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 148 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 148.

149. To the extent Paragraph 149 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 149 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 149.

150. To the extent Paragraph 150 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 150 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 150.

**NINTH CAUSE OF ACTION**  
**Punitive Damages**

151. Answering the allegations of Paragraph 151, BMS repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

152. BMS denies the allegations in Paragraph 152.

153. BMS denies the allegations in Paragraph 153.

154. BMS denies the allegations in Paragraph 154.

155. BMS denies the allegations in Paragraph 155.

156. BMS denies the allegations in Paragraph 156.

157. To the extent Paragraph 157 alleges that Plaintiff suffered any injuries, losses, or damages, BMS lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. To the extent Paragraph 157 alleges any wrongdoing or wrongful acts by BMS or alleges that BMS is liable to Plaintiff or that Plaintiff is entitled to any damages from BMS, BMS denies the same. BMS denies the remaining allegations in Paragraph 157.

**PRAYER FOR RELIEF**

Answering the “WHEREFORE” paragraph under the heading “Prayer for Relief,” including all subparts thereof, BMS admits that Plaintiff seeks the relief requested but denies that Plaintiff is entitled to any relief against BMS whatsoever.

**DEMAND FOR JURY TRIAL**

Answering the paragraph under the heading “DEMAND FOR JURY TRIAL,” BMS admits that Plaintiff demands a jury trial.

**AFFIRMATIVE DEFENSES<sup>1</sup>**

**FIRST AFFIRMATIVE DEFENSE**

Plaintiff’s Complaint fails to state a claim upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

Abilify® (aripiprazole) is, and was at all times, safe for its intended use and not defective or unreasonably dangerous.

**THIRD AFFIRMATIVE DEFENSE**

Without admitting that the product at issue was manufactured and/or sold by BMS, to the extent BMS had any duty with respect to the sale and/or manufacture of the product, such duty was fully discharged by the giving of adequate instructions and warnings concerning its use.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiff’s alleged injuries and/or medical expenses resulted from pre-existing or unrelated medical, psychiatric, genetic, or environmental conditions, diseases, or illnesses.

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<sup>1</sup> BMS asserts the following affirmative defenses without admitting or conceding that all of the affirmative defenses listed below are affirmative defenses for which it carries the burden of proof.

**FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the doctrine of federal preemption.

**SIXTH AFFIRMATIVE DEFENSE**

If Plaintiff suffered injuries and damages by reason of operation of nature or idiosyncratic and/or allergic reaction to the product, used either alone or in combination with any other drug, BMS is not liable.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred or reduced under the principles of assumption of the risk and/or informed consent.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's recovery, if any, from BMS should be reduced, offset, or barred by the contributory or comparative negligence, fault, responsibility, or causation attributable to Plaintiff or to some third party other than BMS.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiff's injuries and damages, if any, were caused in whole or in part by an alteration, change, unintended use, or misuse of the product at issue.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiff's alleged injuries were caused or contributed to be caused by the intervening acts, superseding negligence, and/or subsequent conduct or fault on the part of a person or entity over whom BMS neither had control nor right of control and, therefore, Plaintiff's claims are barred and/or BMS is entitled to an apportionment of damages accordingly.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's alleged damages were not proximately caused by any act or omission of BMS and/or were caused or proximately caused by some person or third party other than BMS for whom BMS is not legally responsible.

**TWELFTH AFFIRMATIVE DEFENSE**

One or more of the claims set forth in Plaintiff's Complaint are barred in whole or in part by the applicable statutes of limitation and/or statutes of repose.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The product at issue was available only through licensed physicians who were provided complete and adequate warnings and instructions consistent with the state of medical and scientific knowledge at the time.

**FOURTEENTH AFFIRMATIVE DEFENSE**

BMS specifically pleads collateral estoppel, res judicata, waiver, laches, and failure to mitigate or minimize damages, if any.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Any acts performed by BMS in the design, manufacture, and marketing of the product at issue were in conformity with the "state of the art" existing at the time of such design, manufacture, and marketing, and public policy should hold that liability not be imposed on BMS for untold risks not known at the time of design, manufacture, and marketing of the product at issue.

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims should be dismissed due to improper venue and/or pursuant to the doctrine of *forum non conveniens*.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are subject to the limitations set forth in the Restatement (Second) of Torts, section 402A, comment k, and/or the Restatement (Third) of Torts.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

BMS had no duty to warn of the possible dangers of using the product at issue, the existence of which are denied, that were not known at the time of manufacture or sale of the product.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine.

**TWENTIETH AFFIRMATIVE DEFENSE**

All of BMS' activities and conduct conformed to all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

The injuries and/or damages claimed by Plaintiff were the result of unavoidable circumstances that BMS could not have prevented.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The injuries and/or damages claimed by Plaintiff were the result of a pre-existing condition unrelated to any conduct of, or products placed in the stream of commerce by, BMS.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

The conduct of BMS in all activities with respect Abilify® has been and is under the supervision of FDA. Accordingly, this action is barred by the doctrine of primary jurisdiction.



**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

The alleged negligent or culpable conduct of BMS, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by the sophisticated user defense.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

The injuries and/or damages claimed by Plaintiff can be attributed to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because the use of the product at issue was generally recognized as safe and effective pursuant to conditions established by FDA and applicable regulations, including packaging and labeling regulations.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

The public interest, benefit, and availability of the product at issue outweigh the risks, if any, resulting from such activities, which were unavoidable given the state of knowledge at the time those activities were undertaken.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Any verdict or judgment rendered against BMS must be reduced by those amounts that have or will, with reasonable certainty, replace or indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, Social Security, worker's compensation, or employee benefit programs.

**THIRTIETH AFFIRMATIVE DEFENSE**

No act or omission of BMS was malicious, willful, wanton, reckless, grossly negligent, or intentional, and therefore any award of punitive damages is barred.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At the time the product left BMS's control, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

BMS is not liable for any harm caused because Abilify® contained an adequate warning as evidenced by its approval by FDA under the Federal Food, Drug, and Cosmetic Act.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Punitive damages are not available to Plaintiff because the drug at issue was subject to premarket approval or licensure by FDA under the Federal Food, Drug, and Cosmetic Act and was approved or licensed.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

BMS did not make to Plaintiff or breach any express or implied warranties and did not breach any warranties created by law. Plaintiff lacked the necessary privity with BMS to maintain claims for breach of warranty, and failed to give timely notice to BMS. Also, BMS is not a seller as defined by N.Y. U.C.C. Law § 2-103 (McKinney), and Plaintiff did not rely on BMS. Therefore, Plaintiff's claims for breach of warranties are barred, fail to state a claim, and should be dismissed with prejudice.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

BMS relies upon all defenses contained in any applicable state statute or law.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

BMS hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in the case and hereby reserves the right to amend this Answer to assert any such defense. BMS also reserves the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein.

**WHEREFORE**, BMS, having fully answered Plaintiff's Complaint, prays that Plaintiff takes nothing by this suit and demands as follows:

1. That Plaintiff's Complaint be dismissed with prejudice on the merits;
2. That BMS recover its costs and disbursements herein expended to the extent permitted under applicable law;
3. That BMS be granted leave to file an amended pleading upon conclusion of reasonable discovery, if necessary; and
4. That BMS be accorded all other relief to which they now or hereafter appear to be entitled.

**JURY DEMAND**

BMS hereby demands a jury trial on all issues so triable.

Dated: March 16, 2016

Respectfully Submitted,

HOGAN LOVELLS US LLP

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*Attorneys for Defendant Bristol-Myers Squibb Co.*

**CERTIFICATE OF SERVICE**

I CERTIFY that on the 16th day of March, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

/s/ Dennis M. Quinio  
Dennis M. Quinio